



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0001]

Drug Development in Pediatric Heart Failure: Extrapolation, Clinical Trial Design, and Endpoints; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled “FDA-University of Maryland CERSI Drug Development in Pediatric Heart Failure: Extrapolation, Clinical Trial Design, and Endpoints.” The purpose of the public workshop is to address challenges related to the evaluation of products in pediatric heart failure including population to study, endpoints, and extrapolation of adult efficacy data. The workshop will also provide a forum for discussion on the use of registry data, as well as alternative trial designs and statistical methods.

DATES: The public workshop will be held on Friday, October 27, 2017, from 8 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at FDA’s White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503A, Silver Spring, MD 20993-0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

FOR FURTHER INFORMATION CONTACT: Jacqueline Yancy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6319, Silver Spring, MD 20993-0002, 301-796-7068, Jacqueline.Yancy@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of this public workshop is to provide an opportunity for relevant stakeholders, including clinicians, academia, industry, and FDA, to discuss alternative trial designs for product development in pediatric heart failure.

II. Topics for Discussion at the Public Workshop

Specifically, the workshop will include application of pediatric extrapolation in drug development for pediatric heart failure and a discussion of alternative approaches to establishing effectiveness in pediatric heart failure, including the use of Bayesian approaches. Cases will be presented to exemplify various approaches.

The agenda is located at

<http://www.cersi.umd.edu/events/index.php?mode=4&id=12500>.

III. Participating in the Public Workshop

Registration: To register for the public workshop, visit the following website:

<http://www.cersi.umd.edu/events/index.php?mode=4&id=12500>. Registrants will receive confirmation when they have been accepted. There will be no onsite registration.

There is a registration fee to attend this public workshop in person. Seats are limited and registration will be on a first-come, first-served basis. The cost to attend in person is as follows:

Category	Cost
Industry Representative	\$50
Nonprofit Organization and Academic Other Than University of Maryland	\$50
University of Maryland, College Park and Baltimore	\$0

Federal Government	\$0
--------------------	-----

If you need special accommodations due to a disability, please contact Jacqueline Yancy (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. There is no registration fee for attending the workshop via the webcast, but registration is still required. Information regarding access to the webcast link is available at <http://www.cersi.umd.edu/events/index.php?mode=4&id=12500>.

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff Office (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: September 15, 2017.

Anna K. Abram,

Deputy Commissioner Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-20106 Filed: 9/20/2017 8:45 am; Publication Date: 9/21/2017]